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Description

This invention relates to a measuring probe for the invasive measurement of blood parameters such as pH, pO_2 or PCO_2 with at least one optical fiber guided in a tubing element and connected at its proximal end to a sensor which is surrounded by a tube-like sheath.

Probes for the invasive measurement of blood parameters consist of at least one sensor comprising an optical fiber, said fiber ending up with a gel zone containing a dye. The optical density or another optical parameter of said dye varies with the blood parameter (such as pH) to be measured. On the other side of the dye-containing gel, a reflector is positioned. The end of the fiber, the gel and the reflector are surrounded by a semi-permeable envelope (for example, a hydrogen ion permeable envelope in the case of a pH sensor) to Keep the gel in place.

Light from this optical fiber passes the dye-containing gel, is reflected by said reflector, passes the gel again and is transmitted through the optical fiber to an appropriate detector which measures light attenuation or changes in other optical parameters caused by the dye. This attenuation or change is a function of the blood parameter to be measured, and the relation between attenuation, absorbance or the change of another optical parameter and the blood parameter is well-known.

Such a probe can be introduced in the patient's artery to measure – depending on the dye and/or the selected semi-permeable envelope various blood parameters such as pH, pO_2 or PCO_2.

For further details of fiber optic pH measurement, reference is made to the essay "A Miniature Fiber Optic pH Sensor for Physiological Use" published in the Journal of Biomechanical Engineering, Hay 1980, pg. 141. For a break-down on the probes, see e.g. "IEEE Transactions on Biomedical Engineering", Vol. BME-33, No.2, Feb. 1986, p.117.

As the measuring probe is introduced into the artery, it is a major problem to guarantee absolute mechanical stability for the assembled probe. It has to be ensured that no part of the probe, in particular of the probe tip, can break off or be sheared off as such an incident could lead to embolism and, therefore, even to the death of the patient.

Up to now, the mechanical stability of such a probe is only guaranteed by the connection between the tubing element and the sheath covering the probe tip. With respect to stability, this is the most sensitive portion of the probe as tearing-off of the sheath would leave the same in the artery of the patient.

It is a major objective of the present invention to provide a measuring probe which guarantees complete mechanical stability and, in particular, a completely firm connection between the tubing element and the sheath.

According to the invention, this problem is solved for a measuring probe of the type described above by the following features:

(1.1) The sheath is closed at its outer end by locking means,

(1.2) a wire is fastened to the inner side of said locking means,

(1.3) said wire is guided in the tubing element and

(1.4) said wire is fastened to a distal portion of the probe, preferably to said tubing element or to connecting means.

Such a probe comprises a wire which is - as well as the optical fiber(s) leading to the sensor(s) and in parallel to them - guided in the tubing element. The wire then passes the sheath (in parallel to the sensor(s)) and is fastened to the locking means (e.g., a metal cap) which closes the sheath at its outer end and is preferably connected with the same.

The wire is preferably carried to the outside through a hole in the tubing element and glued to the outer side of the tubing element by means of a plastic part. This is performed in a distal portion of the probe (in the terms of this description, "distal end" of the probe means those portions of the probe which are not to be introduced into the patient's body; "proximal end" means the end of the probe which is near the body of the patient, i.e. to be introduced into the patient's artery, and "outer end" of the sheath means its most proximal end).

Alternatively, the wire may also be fastened to a connector or the like; in this case, the optical fiber is also connected to said connecting means, said optical fiber providing light guidance from and to a monitor and the wire ensuring strain relieving of the probe.

Such a measuring probe ensures a very tight mechanical connection between all probe components. In particular, the sheath cannot get off the tube, and no break of the probe distal to the sensor tip can occur (measuring probes according to the state of the art could even break off in this region which is also partially introduced into the patient's artery). The strain relieving wire also ensures that no break of a sensor or an optical fiber can occur as all or at least most tension forces are absorbed by the wire parallel to the sensor(s)/optical fiber(s).

This is achieved by the basic idea of an additional wire guided in the tubing element in parallel to the optical fibers and fixed at both ends to the outer sheathing (the sheath at the proximal end and the tubing or the connector at the distal end). Neither the sheath, the tubing, the sensor(s) nor the optical fiber(s) have to absorb major tension forces, and, therefore, the new probe is absolutely save for medical applications. It is understood that the wire (and, of course, the other components of the probe) must meet the requirements for medical applications. For example, stainless steel may be well-suited for this purpose. A selection of wires for medical applications can be found in "Fabricating Medical Components from Wire", by Terry L. Bartel, MD&DI, September 1987, pg. 66 ff. A preferred wire for the present application is the "MP35N" wire, cf. Tables I and II in that essay.

Preferably, the sheath and/or the locking means consist of metal, in particular stainless steel. Al-

though this is not mandatory, it increases the mechanical stability of the probe tip; furthermore, metal is easy to sterilize, and the metal/metal connections (e.g., sheath to locking means and locking means to wire) may be welded or soldered. This is of particular importance for the connection between the wire and the locking means as the wire can only fulfill its strain relieving function if this connection is reliable. Still another solution may be selected, e.g. to embed the wire in a plastic locking means.

Advantageously, the locking means has a sphere-like contour. As it is important that the outer contour of the locking means fits well in a patient's artery without violating it, metal as the basic material for the locking means has the advantage that finishing can be performed after the attachment of the locking means to the sheath. Preferably, this finishing is performed by electropolishing which ensures that the outer contour of the locking means as well as its (welded or soldered) connection to the sheath is extremely smooth.

The invention further refers to a method for manufacturing a measuring probe of the type described above wherein the sheath as well as the locking means consist of metal. According to this method, the wire is first passed through said sheath, and then said locking means is welded or soldered to said sheath as well as to said wire in a single welding or soldering process. This method ensures that both relevant connections (locking means to sheath and wire to locking means) can be welded or soldered and is - due to the fact that only a single manufacturing step is necessary - very easy to perform. A very solid and smooth welding connection even in the small dimensions of such a measuring probe may be obtained if welding is performed by a laser, preferably in an argon atmosphere. As just mentioned, the outer side of the locking means and its connection to the sheath may be electropolished afterwards to remove any projecting burrs.

For the purpose of measuring blood parameters, the sheath must have openings or the like to allow ions or molecules to come into contact with the sensors. As just outlined above, it is evident that a patient's artery is not injured by the outer contour of the probe. Therefore, according to a further advantageous aspect of the invention, the edges of the window(s) of the sheath are rounded. It has turned out in a lot of tests that the best method to obtain such rounded edges is to use the spark erosion technique.

In the accompanying drawings, a preferred embodiment of the present invention is shown. More features and advantages are contained in the following description in which these drawings are explained.

In the drawings,

Fig. 1a is a side view of the probe tip of a measuring probe according to the invention without tubing element and without sensors,

Fig. 1b is a longitudinal section along line Ib-Ib of Fig. 1a,

Fig. 1c is a cross section along line Ic-Ic of Fig. 1b,

Fig. 2 is an outside view of the probe tip of an assembled measuring probe,

Fig. 3 depicts a longitudinal section of a single sensor and its associated optical fiber,

Fig. 4 is a cross section of the probe tip of an assembled measuring probe,

Fig. 5 is a longitudinal section of the sheath illustrating the process of manufacturing its windows,

Fig. 6 depicts a schematic diagram of a complete measuring probe, and

Fig. 7 depicts a schematic diagram of another measuring probe.

Fig. 1a depicts a probe tip 1 of a measuring probe for the invasive measurement of blood parameters. This probe tip is not yet completely assembled. A metal sheath 2, closed at its outer end by sphere-like locking means 3, is provided for introduction into a patient's artery. Sheath 2 further provides three windows 4a, 4b and 4c with inclined edges. A metal wire 5 is provided for strain relieving.

Fig. 1b - which is a cross section along line Ib-Ib of Fig. 1a - depicts the contour of sphere-like locking means 3. This locking means also consists of metal, in particular stainless steel. In the manufacturing process, wire 5 is first passed through sheath 2 (from the right to the left) and then welded in an argon atmosphere by a laser to locking means 3. Simultaneously, locking means 3 is welded to sheath 2 (same manufacturing process). Finally, the outer contour of locking means 3 is electropolished; in particular, burrs protruding at the connection line 3' between locking means 3 and sheath 2 are removed. Although indicated as 3' the connection line between locking means 3 and sheath 2 is no longer visible after electropolishing. Sheath 2, locking means 3 and wire 5 consist of the same material and form an integral part after welding or soldering. Locking means 3 may - as in the present example - also be formed from the material of wire 5 and sheath 2 upon welding or soldering.

Sheath 2 further defines a recess 6 for the introduction of a flexible tubing as will be explained below. Windows 4a to 4c allow the blood to reach the sensors as will be also explained below.

Wire 5 serves as a strain relieving member and is therefore not only attached to locking means 3 at the outer end of sheath 2, but also at its distal end to a connector or to the Kevlar fibers of the tubing.

Fig. 1c depicts a cross section along line Ic-Ic of Fig. 1b. This cross section shows openings or windows 4a to 4c in detail.

Fig. 2 depicts an outside view of a completely assembled probe tip 1. Sheath 2 is connected (e.g. by an adhesive or glue) to a tubing 7. Sheath 2 contains wire 5 as well as three sensors one of which (8) is shown in Fig. 2 (with respect to the other sensors, see Fig. 4).

The details of a sensor shall now be discussed in detail with reference to Fig. 3. This figure depicts a longitudinal section through a sensor and the associated optical fiber. With reference to Fig. 2, the left and right side are reversed in Fig. 3.

Light guided in an optical fiber 9 reaches a dye-containing gel 10 in sensor 8. The absorption spec-

trum of dye 10 is dependent on the parameter to be measured. For a pH sensor, the dye may be phenol red.

The transmitted light is then reflected at reflector 11. Preferably, this reflector is made of metal such as platinum or stainless steel, the surface of this metal being polished on the side of gel 10. The reflected light passes dye-containing gel 10 again and is directed back through optical fiber 9 and appropriately received by and processed in a monitor. The whole system is packed in a selective membrane or envelope 12, this membrane being permeable for the ions or gas molecules to be measured - in case of a pH electrode, for hydrogen ions - , so that these ions/gas molecules can reach the dye-containing gel. Membrane 12 is fastened on optical fiber 9 and reflector 11 by a glue 13. The preferred material for membrane 12 is a hydrophilic material such as cellulose.

Now returning to Fig. 2, it is evident that windows 4a to 4c are required to allow ions or gas molecules to reach the selective membranes and, consequently, the dye-containing gel of the sensors.

Fig. 4 is a cross section of the measuring probe in the region of sheath 2 near its outer end, i.e. outside windows 4a to 4c. As just explained, this sheath contains wire 5 and a sensor 8 (e.g., a pH sensor) of which reflector 11 and envelope 12 can be seen in Fig. 4. Further sensors shown in Fig. 4 are a pO_2 sensor 14 and a pCO_2 sensor 15 which are basically equal to sensor 8 (but, of course, contain other dyes and/or envelopes depending on the parameter to be measured). The sheath itself is filled with a glue or adhesive 16 which holds the sensors and the wire in place.

Fig. 5 is a longitudinal section of sheath 2 and illustrates manufacturing of the rounded edges of window 4b. A wire 17 is moved in a direction perpendicular to its axis (cf. arrow 18) and thereby provides a window 4b with rounded edges. Dependent on the movement of wire 17, the edges of window 4b may be given any desired profile.

Fig. 6 depicts a schematical outside view of the complete measuring probe. Tubing 7 is partially broken away to show wire 5 and membrane 12 covering optical fiber 9. The other optical fibers are not shown in Fig. 6.

A connector 19 is provided for connection with a monitor which contains a light source and a light receiving means. All optical fibers and wire 5 are fastened to said connector, the optical fibers to ensure light guidance and wire 5 to ensure strain relieving of the measuring probe.

Proximal end 20 of the measuring probe (the probe tip) is intended for introduction into a patient's artery, whereas the other end 21 is - as just mentioned - to be connected with a monitor.

Fig. 7 depicts another way of fastening the wire. The distal portion (which is not to be introduced into the patient's artery) of tubing 7 is thicker (indicated by reference number 22). In this portion, wire 5 runs through a hole in the tubing (see the broken-away region in Fig. 7) and is fixed to the outside by means of a glued plastic sleeve 23. This solution has - with reference to the embodiment of Fig. 6 - the advantage that there is no danger of an unwanted electrical connection between the monitor and the probe.

Claims

1. Measuring probe for the invasive measurement of blood parameters such as pH, pO_2 or pCO_2, with at least one optical fiber (9) guided in a tubing element (7) and connected at its proximal end to a sensor (8) which is surrounded by a tube-like sheath (2), in which at least one window (4) is proofted, characterized in that

(1.1) said sheath (2) is closed at its outer end by locking means (3),

(1.2) a wire (5) is fastened to the inner side of said locking means (3),

(1.3) said wire (5) is guided in said tubing element (7) and

(1.4) said wire (5) is fastened to a distal portion of the probe, preferably to said tubing element (7) or to connecting means (19).

2. Measuring probe according to claim 1, characterized in that said sheath (2) consists of metal.

3. Measuring probe according to claim 2, characterized in that said locking means (3) consists of metal, preferably of sphere-like contour, which is welded or soldered to said sheath (2).

4. Measuring probe according to at least one of the preceding claims wherein said locking means (3) consists of metal, characterized in that said wire (5) is welded or soldered to said locking means (3).

5. Method for manufacturing a measuring probe according to at least one of the preceding claims wherein said sheath (2) as well as said locking means (3) consist of metal, characterized in that said wire (5) is first passed through said sheath (2), and then said locking means (3) is welded or soldered to said sheath (2) as well as to said wire (5) in a single welding or soldering process.

6. Method according to claim 5 with welded connections, characterized in that welding is performed by a laser, preferably in an argon atmosphere.

7. Method according to claim 5 or 6, characterized in that the outer side of said locking means (3) is electropolished.

8. Measuring probe according to at least one of the preceding claims wherein said sheath (2) comprises at least one window (4a, 4b, 4c), characterized in that the edges of said window (4a, 4b, 4c) are rounded.

9. Method for manufacturing a measuring probe according to claim 8, characterized in that the window (4a, 4b, 4c) in said sheath (2) is manufactured by spark erosion.

Patentansprüche

1. Meßfühler zur invasiven Messung von Blutparametern wie pH, pO_2 oder pCO_2, mit wenigstens einer optischen Faser (9), die in einem Schlauchelement (7) geführt ist und die an ihrem körpernahen Ende mit einem Sensor (8) verbunden ist, der von einer schlauchartigen Ummantelung (2), die wenig-

stens ein Fenster (4) aufweist, umgeben ist, dadurch gekennzeichnet, daß

(1.1) die Ummantelung (2) an ihrem äußeren Ende durch Verschlußmittel (3) abgeschlossen ist,

(1.2) ein Draht (5) an der inneren Seite der Verschlußmittel (3) befestigt ist,

(1.3) der Draht (5) in dem Schlauchelement (7) geführt ist und

(1.4) der Draht (5) an einem körperfernen Teil des Fühlers befestigt ist, vorzugsweise an dem Schlauchelement (7) oder an Verbindungsmitteln (19).

2. Meßfühler nach Anspruch 1, dadurch gekennzeichnet, daß die Ummantelung (2) aus Metall besteht.

3. Meßfühler nach Anspruch 2, dadurch gekennzeichnet, daß die Verschlußmittel (3) aus Metall bestehen, vorzugsweise von kugelartiger Gestalt, das an die Ummantelung (2) angeschweißt oder angelötet ist.

4. Meßfühler nach wenigstens einem der vorhergehenden Ansprüche, bei dem die Verschlußmittel (3) aus Metall bestehen, dadurch gekennzeichnet, daß der Draht (5) an die Verschlußmittel (3) angeschweißt oder angelötet ist.

5. Verfahren zur Herstellung eines Meßfühlers nach wenigstens einem der vorhergehenden Ansprüche, bei dem sowohl die Ummantelung (2) als auch die Verschlußmittel (3) aus Metall bestehen, dadurch gekennzeichnet, daß der Draht (5) zuerst durch die Ummantelung (2) geführt wird, und daß dann die Verschlußmittel (3) sowohl an die Ummantelung (2) als auch an den Draht (5) in einem einzigen Schweiß- oder Lötprozeß angeschweißt oder angelötet werden.

6. Verfahren nach Anspruch 5 mit geschweißten Verbindungen, dadurch gekennzeichnet, daß die Schweißung mit einem Laser durchgeführt wird, vorzugsweise in einer Argonatmosphäre.

7. Verfahren nach Anspruch 5 oder 6, dadurch gekennzeichnet, daß die Außenseite der Verschlußmittel (3) elektropoliert wird.

8. Meßfühler nach wenigstens einem der vorhergehenden Ansprüche, bei dem die Ummantelung (2) wenigstens ein Fenster (4a, 4b, 4c) aufweist, dadurch gekennzeichnet, daß die Kanten dieses Fensters (4a, 4b, 4c) abgerundet sind.

9. Verfahren zur Herstellung eines Meßfühlers nach Anspruch 8, dadurch gekennzeichnet, daß das Fenster (4a, 4b, 4c) in der Ummantelung (2) durch Funkenerosion hergestellt wird.

Revendications

1. Sonde de mesure pour la mesure par pénétration de paramètres sanguins, comme pH, pO_2 ou pCO_2, comportant au moins uns fibre optique (9) guidée dans un élément de tube (7) et reliée à son extrémité proximale à un capteur (8) qui est entouré par uns gaine tubulaire (2) dans laquelle est ménagée au moins une fenêtre (4), caractérisée en ce que

(1.1) ladite gaine (2) est fermée à son extrémité extérieure par des moyens de verrouillage (3),

(1.2) un fil (5) est fixé sur le côté intérieur desdits moyens de verrouillage (3),

(1.3) ledit fil (5) est fixé dans ledit élément de tube (7) et

(1.4) ledit fil (5) est fixé à une partie distale de la sonde, de préférence audit élément de tube (7) ou à des moyens de 1 liaison (19).

3. Sonde de mesure selon la revendication 1, caractérisée en ce que ladite gaine (2) est en métal.

3. Sonde de mesure selon la revendication 2, caractérisée en ce que lesdits moyens de verrouillage (3) sont en métal, de préférence d'un contour de type sphérique, qui est soudé ou brasé sur ladite gaine (2).

4. Sonde de mesure selon l'une au moins des précédentes revendications dans laquelle lesdits moyens de verrouillage (3) sont en métal, caractérisée en ce que ledit fil (5) est soudé ou brasé sur lesdits moyens de verrouillage (3).

5. Procédé de fabrication d'une sonde de mesure selon l'une au moins des précédentes revendications dans lequel ladite gaine (2) ainsi que ledit moyen de verrouillage (3) sont en métal, caractérisé en ce que ledit fil (5) traverse d'abord ladite gaine (2), et qu'ensuite ledit moyen de verrouillage (3) est soudé ou brasé sur ladite gaine (2) ainsi que sur ledit fil (5) en un seul processus de soudage ou de brasage.

6. Procédé selon la revendication 5, comportant des liaisons soudées, caractérisé en ce que le soudage est effectué par un laser, de préférence en atmosphère d'argon.

7. Procédé selon la revendication 5 ou 6, caractérisé en ce que le côté extérieur dudit moyen de verrouillage (3) est poli par électrolyse.

8. Sonde de mesure selon l'une au moins des précédentes revendications dans laquelle ladite gaine (2) comprend au moins une fenêtre (4a, 4b, 4c), caractérisée en ce que les bords de ladite fenêtre (4a, 4b, 4c) sont arrondis.

9. Procédé de fabrication d'une sonde de mesure selon la revendication 8, caractérisé en ce que la fenêtre (4a, 4b, 4c) de ladite gaine (2) est fabriquée par érosion par étincelage.

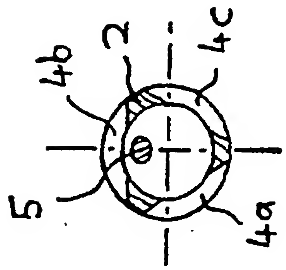

Fig. 1c

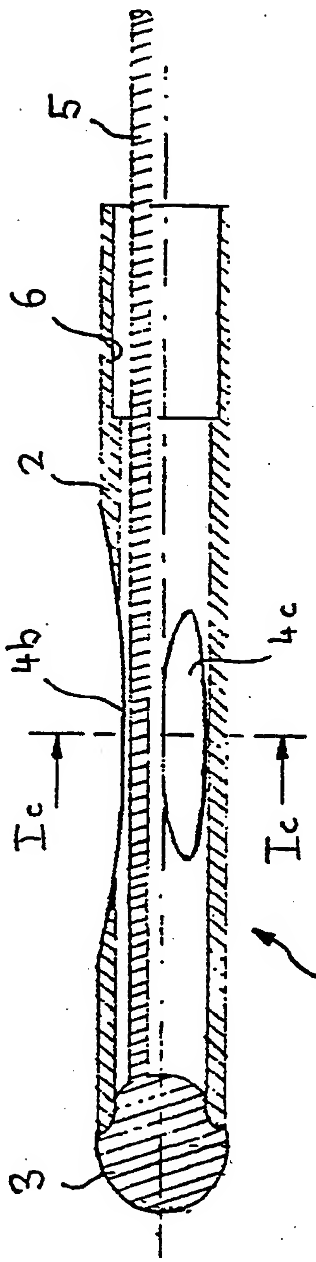

Fig. 1b

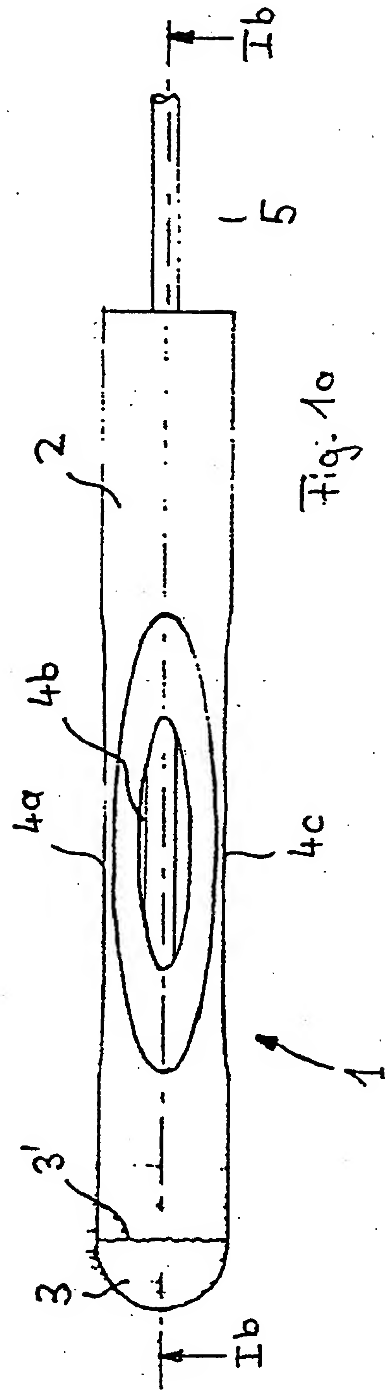

Fig. 1a

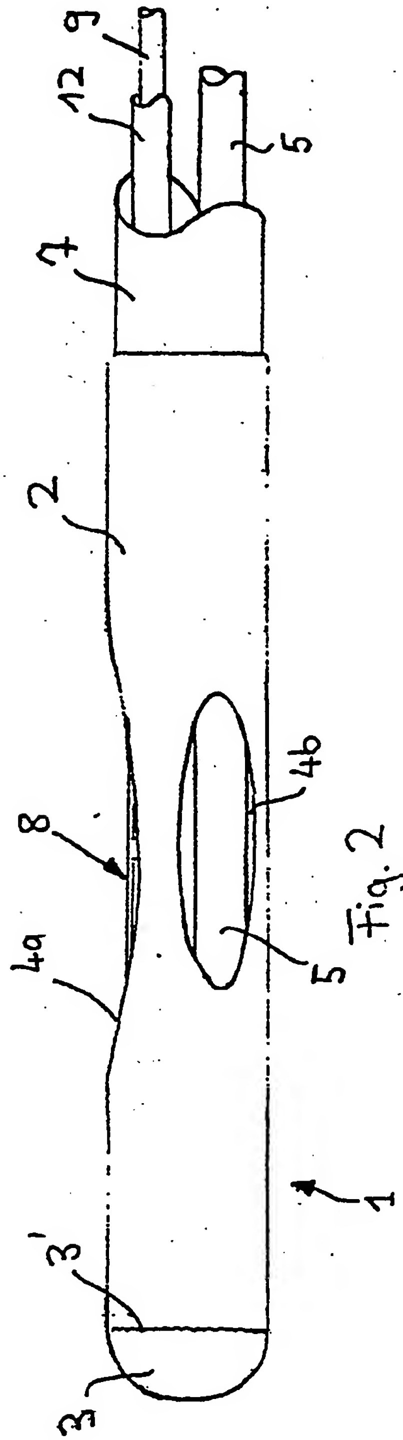

Fig. 2

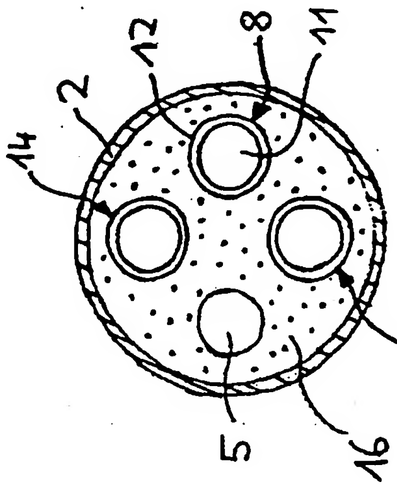

Fig. 4

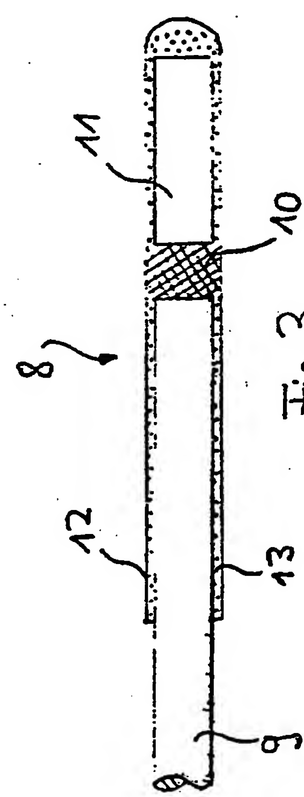

Fig. 3

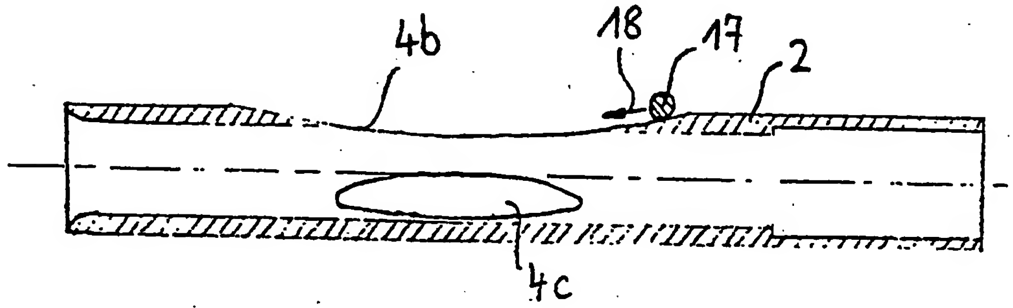

Fig. 5

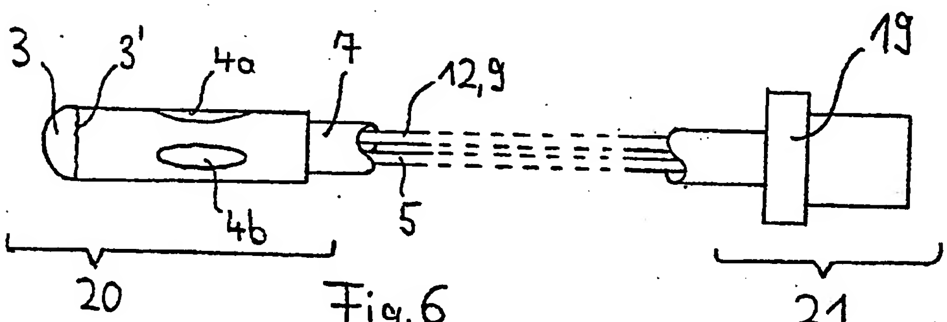

Fig.6

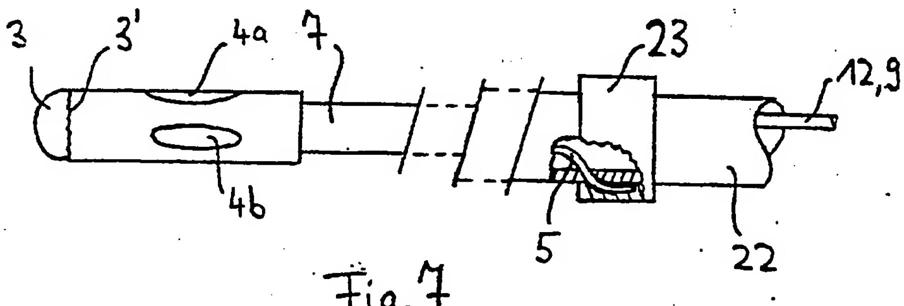

Fig. 7

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